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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,135	07/28/2003	Ben A. Hitt	CORR-003/01US 302031-2044	4522
22903 7590 07/23/2007 COOLEY GODWARD KRONISH LLP ATTN: PATENT GROUP Suite 500 1200 - 19th Street, NW WASHINGTON, DC 20036-2402			EXAMINER CLOW, LORI A	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 07/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/628,135

Applicant(s)

HITT ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-7, 13-27, 29, 31, 32 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-7, 13-27, 29, 31, 32 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/6/06; 4/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 19 April 2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 4-7, 13-27, 29, 31, 32, and 35 are currently pending. Claims 1-3, 8-12, 28, 30, 33, and 34 have been cancelled.

Information Disclosure Statement

The Information Disclosure Statement filed 6 April 2006 has been partially considered. References 77, 80, 86, 139 and 154 have not been considered, as they lack a publication date.

The Information Disclosure Statement filed 19 April 2007 has been considered in full.

Signed copies of PTO forms 1449 are included in this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 35 remains rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 35 is directed to a method of evaluating results for a bioassay that generates spectral data, which does not recite either a physical transformation of matter nor a practical application [i.e. concrete, tangible, and useful result]. Instant claim 35 recite steps comprising

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providing a location in an n-dimensional space of a control centroid and a test centroid and comparing a test centroid to a control to determine displacement in n-dimensional space. No description or definition for "providing" data or "comparing" centroids is provided in the specification such that these would be interpreted as a physical steps, therefore the claimed method steps do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a concrete, tangible, and useful result (i.e. a practical application). However, no actual, concrete result is recited in the claims, nor is any useful result "produced" in a tangible form useful to one skilled in the art.

Note: As independent claims 15, 21, and 25 recite physical steps, such as preparing a mixture of molecules (claim 15), retrieving a test aliquot and analyzing data from the aliquot using a bioassay process (claim 21), and generating test spectral data from a second aliquot (claims 25), the claims are considered statutory and are not rejected herein.

Response to Applicant's Arguments

1. Applicant states that claim 35, as amended, now recites limitations drawn from claim 13, such that claim 35 requires the determination of a practical outcome, i.e., whether the bioassay is or is not functioning properly.

This is not persuasive, as the steps of the method do not provide for a tangible result. The revised Guidelines state that the focus is "not on whether the steps taken to achieve a particular result are useful, tangible, and concrete, but rather on whether the **final result** achieved by the claimed invention is useful, tangible, and concrete." In the instant case, claim 35 results in a step

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of "determining" displacement, and thus does not result in a "tangible" result that it is useful to one skilled in the art. For the above reasons, the instant claims are not statutory.

This rejection could be overcome by amending the claims to recite that a result of the method is "displayed" or "outputted" (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay), provided such is supported in the specification as originally filed. For an updated discussion of statutory considerations, see the revised Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV (Latest Revision August 2006).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7, 13-27, 29, 31, 32, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *The rejections set forth below are necessitated by amendment.*

Claims 15, 21, and 25 recite, "as an indication of whether the bioassay has generated unreliable results". It is unclear what is intended by indicating unreliable results. Is it **if** the displacement in the n-dimensional space of the test centroid exceeds a predetermined distance **then** the bioassay is deemed unreliable or some other indication? Clarification through clearer claim language is requested.

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Claim 35 recites, “wherein the determining whether the test centroid is within a predetermined distance includes”. There is insufficient antecedent basis in the claim for “wherein **the** determining whether the test centroid is within a predetermined distance”. The claim recites providing a location in n-dimensional space of a test centroid, comparing a test centroid to the control to determine displacement, but no recitation of determining whether the test is within a predetermined distance. Clarification is requested.

Conclusion

The outstanding rejection under 35 USC 101 is maintained.

New rejections, necessitated by amendment are applied under 35 USC 112, 2nd paragraph.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

July 13, 2007

Lori A. Clow, Ph.D.

Primary Patent Examiner

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